

### **REMARKS**

Reconsideration is respectfully requested. The present amendment is submitted in response to the Office Action dated April 10, 2002 and pursuant to a telephone interview with the Examiner on July 16, 2002.

In the Office Action, claims 1-18 and 33-34 were rejected on various bases. In this Response, claims 11 and 14 have been canceled, and claims 1 and 17 have been amended to recite that the first water-erodable adhesive layer is "free of a plasticizer" to more particularly point out and distinctly claim the subject matter of the Applicants' invention. Support for this amendment may be found in the instant specification on page 10, lines 7-12, and in Examples 12-14, among other places.

After entry of the present amendment, claims 1-10, 12-13, 15-18, and 33-34 will be pending.

### **Examiner Interview**

Applicants thank the Examiner for the most helpful interview via telephone on July 16, 2002 with Thomas Ciotti and the undersigned. The amendment and remarks submitted herewith are in accordance with that discussion.

### **Rejection of Claims 1-7, 9-15, 17, and 18 Under 35 U.S.C. § 102(b)**

Claims 1-7, 9-15, 17, and 18 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,552,751 to Inaba et al. (equivalent to EPA 0050480). In particular, the Office Action states:

" Inaba et al teach a three-layer composition comprising an outer control release layer comprising polyvinyl pyrrolidone and hydroxy alkyl cellulose (Figure 1 and claim 1A). A drug-storing layer comprising hydroxypropyl cellulose is disclosed (claims 8). Glycerin is specified in (claim 1C). Prostaglandins, known for lowering blood pressure, are disclosed (column 1 line 48)."

“Vinyl acetate is specified (claim 1B). As to the claimed adhesive layer, this property must be inherent in the Inaba et al. composition because it possesses the same polymer as that claimed as an adhesive, namely, polyvinyl pyrrolidone.”

“Applicants argue that Inaba et al. only teaches 3 layers. However, applicants’ “comprising” language encompasses more than two Layers.”

“Similarly, applicants argue that Inaba et al. teaches water-insoluble polymers. However, applicants’ “comprising” language includes such polymers.”

Inaba et al. teach a multiple layered film preparation having water-soluble polymers, water-insoluble polymers, at least one plasticizer, and a prostaglandin. The plasticizer is present in all drug layers, i.e., both the drug storing layer(s) and the drug controlling layer(s). Furthermore, the plasticizers are described as biologically inactive and conventional.

Inaba et al. is distinguished by the present amendment to the claims. The claims have been amended to recite that the adhesive layer is free of plasticizer. Inaba et al. do not suggest or imply an adhesive layer that is free of plasticizer.

Therefore, after entry of the present amendment, Applicants respectfully request withdrawal of the rejection.

#### **Rejection Under 35 U.S.C. § 112, First Paragraph**

Claim 34 has been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically the Office Action states:

“Nowhere in the specification do applicants disclose a flavoring agent.”

Applicants disagree. The specification at page 18, lines 19-21, states, “plasticizers, flavoring and coloring agents, and preservatives may also be included in the pharmaceutical delivery device of the present invention in the adhesive layer, the backing layer, or both.”

Furthermore, in Examples 7 and 37, a peppermint flavorant was incorporated into the non-adhesive backing layer. Therefore, flavoring agents are disclosed, and withdrawal of the rejection is respectfully requested.

**Rejection of Claims 1-6, 9, 11, 12, 14, 15, 17, and 18 Under 35 U.S.C. § 102(b)**

As discussed in previous telephone communications with the Examiner on July 16, 2002, this rejection was intended to cover claims 1-9, 11, 12, 14, 15, 17, and 18. Accordingly, for purposes of this Response, Applicants will consider that this rejection applies to claims 1-9, 11, 12, 14, 15, 17, and 18 and request correction if this is incorrect.

Claims 1-9, 11, 12, 14, 15, 17, and 18 have been rejected under 35 U.S.C. § 102(b) as being anticipated by WO 95/05416 ('416). Specifically, the Office Action states:

“‘416 teaches a composition comprising an adhesive layer and other layers, which are water-soluble and contain an active (Abstract).”

“Hydroxypropyl cellulose in combination with PVP is disclosed (page 12 line 29 page 13 line 1). Thicknesses are specified (page 13 lines 11-12). Hydroxypropyl cellulose is disclosed in a second layer (page 15 lines 7-16). An overlapping adhesive layer is specified (page 30 lines 16-21). Anesthetics are specified (page 9 line 21).”

Applicants disagree. WO 95/05416 ('416) to Biegajski et al. describes a pressure-sensitive adhesive that is made tacky by the addition of a water-soluble plasticizer. In one embodiment, the pressure-sensitive adhesive is used in the adhesive layer of a laminated device for the controlled release of a substance. Examples of suitable plasticizers that are disclosed include glycerin, sorbital, any of the glycols, polysorbate 80, triethyl titrate, acetyl triethyl titrate, and tributyl titrate.

As described *supra*, the claims have been amended to recite that the adhesive layer is “free of plasticizer”. Biegajski et al. do not teach or suggest an adhesive layer lacking plasticizer. Furthermore, Applicants would like to point out that in Examples 12-14, among

others, plasticizers are not included in the adhesive layer. Thus, Biegajski et al. is distinguished by the present amendment to the claims.

Accordingly, after entry of the present amendment, Applicants respectfully request withdrawal of the rejection.

### **SUMMARY**

Applicants have responded to each matter of substance raised in this Office Action and believe that the case is in condition for allowance. Should the Examiner have any requests, questions, or suggestions, he is invited to contact the Applicants' representative at the number listed below.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made**".

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 359872000821. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the Claims:**

1. (Three Times Amended) A pharmaceutical carrier device comprising a layered flexible film having a first water-erodable adhesive layer to be placed in contact with a mucosal surface, a second, water-erodable non-adhesive backing layer, and a pharmaceutical incorporated with said first layer, said second layer, or both layers, wherein said first water-erodable adhesive layer comprises a film-forming polymer and a bioadhesive polymer, and is free of a plasticizer, and wherein said second water-erodable non-adhesive backing layer comprises a film-forming polymer.

17. (Three Times Amended) A layered flexible film disk which adheres to mucosal surfaces for the localized delivery of a pharmaceutical, comprising a first water-erodable adhesive layer and a second, water-erodable non-adhesive backing layer, wherein said pharmaceutical or combination of pharmaceuticals is incorporated with said first adhesive layer, or said second non-adhesive backing layer, or both said first adhesive layer and said second non-adhesive backing layer, and wherein said first water-erodable adhesive layer comprises a film-forming polymer and a bioadhesive polymer, and is free of a plasticizer, and wherein said second water-erodable non-adhesive backing layer comprises a film-forming polymer, said layered flexible film having a total thickness of from 0.1 mm to 1 mm.